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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/511,988

04/25/2005

Judith Ann Clements

21415-0012US1

9135

26633 7590 06/28/2007  
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EXAMINER

YAO, LEI

ART UNIT

PAPER NUMBER

1642

MAIL DATE

DELIVERY MODE

06/28/2007

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/511,988	<b>Applicant(s)</b> CLEMENTS, JUDITH ANN	
	<b>Examiner</b> Lei Yao, Ph.D.	<b>Art Unit</b> 1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 21 October 2004.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 58-98 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 58-98 are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

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**DETAILED ACTION*****Election/Restrictions***

It is noted that applicants had cancelled claims 1-57 and add new claims 58-98 in preliminary amendment, filed on 10/21/2004. However, newly added claims 59-88 are depending the cancelled claims. In order to precede the prosecution, currently independent claim 1 is considered as claim 58 and the dependent claims will be grouped based on the subject matter of the claims. Applicant is required to amend the claims to change the correct dependency in reply this Office action.

Restriction is required under 35 U.S.C. 121 and 372.

Restriction to one of the following inventions is required under 35 U.S.C. 121:

Group 1, claim 58-98, drawn to a method of detecting the presence or diagnosing the risk of prostate cancer in a patient, comprising detecting in a biological sample obtained from the patient a level or functional activity of an aberrant expression of gene product, wherein the product is PSA RP2 transcript 1 and the polypeptide encoded by the transcript.

Group 2, claim 58-98, drawn to a method of detecting the presence or diagnosing the risk of prostate cancer in a patient, comprising detecting in a biological sample obtained from the patient a level or functional activity of an aberrant expression of gene product, wherein the product is PSA RP2 transcript 2 and the polypeptide encoded by the transcript.

Group 3, claim 58-98, drawn to a method of detecting the presence or diagnosing the risk of prostate cancer in a patient, comprising detecting in a biological sample obtained from the patient a level or functional activity of an aberrant expression of gene product, wherein the product is KLK2 and the polypeptide encoded by the transcript.

It is noted that the dependent claims 59-71 comprise different SEQ ID Nos. However, the relationship between the SEQ ID Nos and gene products stated above have not been identified.

Applicant is required to elect one from groups 1-3 with corresponding SEQ ID Nos (see below).

Further election required under 35 U.S.C. 121

MPEP § 803.04 discusses restriction between nucleotide sequences in nationally filed applications filed under 35 U.S.C. 111. This application is an internationally filed application filed under 35 U.S.C. 371 and is subject to the rules discussed under MPEP § 1850 (see the last paragraph under MPEP § 803.04, which references the appropriate section for internationally filed applications). Under Markush practice for international applications, the following criteria are required:

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(A) the alternatives have a common property or activity and (B) a common core structure is present; or

(C) in cases where the core structure cannot be the unifying criteria, all alternatives must belong to the same recognized class of chemical compounds, that is, that the same result will be achieved when one member of the Markush group is substituted for another.

In the instant case, each product of transcript (transcript 1, transcript 2 or KLK2) showing is structural distinct product, which cannot hybridize to the other transcript or do not shear the common core structure or activities with the other proteins. Therefore, the transcript or proteins do not meet the criteria for (A) and (B). Also, the product of transcript comprising peptide do not meet criteria (C) because the same result is not achieved when each product of transcript used for treating prostate cancer is substituted for the product of other transcript. Since the instant product of transcript do not share the same or corresponding special technical feature under the specific criteria for Markush practice, the product of transcript lack unity of invention and are not considered alternative species to one another. Therefore, applicant's proposed species election would be improper.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48 (b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48 (b) and by the fee required under 37 CFR 1.17 (i).

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lei Yao, Ph.D. whose telephone number is 571-272-3112. The examiner can normally be reached on 8am-6.00pm Monday-Thursday.

Any inquiry of a general nature, matching or file papers or relating to the status of this application or proceeding should be directed to Kim Downing for Art Unit 1642 whose telephone number is 571-272-0521

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shanon Foley can be reached on 571-272-0898. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Lei Yao,  
Examiner  
Art Unit 1642

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